



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/690,115	10/21/2003	Richard L. Apodaca	PRD2033NP	3740

27777 7590 06/04/2007
PHILIP S. JOHNSON
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER

COLEMAN, BRENDA LIBBY

ART UNIT	PAPER NUMBER
----------	--------------

1624

MAIL DATE	DELIVERY MODE
-----------	---------------

06/04/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/690,115

Applicant(s)

APODACA ET AL.

Examiner

Brenda L. Coleman

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,22,23,25-30,41-43,47-53 and 56-62 is/are pending in the application.
- 4a) Of the above claim(s) 47-50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,22,23,25-30,41-43,51-53 and 56-62 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 11/24/06 & 4/2/07.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Claims 1-4, 22, 23, 25-30, 41-43, 47-53 and 56-62 are pending in the application.

This action is in response to applicants' amendment filed March 14, 2007.

Claims 1, 13, 15, 27, 28, 37 and 38 have been amended.

Response to Amendment

Applicant's amendments filed March 14, 2007 have been fully considered with the following effect:

1. The applicant's amendments and arguments are sufficient to overcome the 35 USC § 112, first paragraph rejection, labeled paragraph 1) maintained in the last office action, which is hereby **withdrawn**.
2. The applicant's amendments and arguments are sufficient to overcome the 35 USC § 112, second paragraph rejection, labeled paragraph 2i) maintained in the last office action, which is hereby **withdrawn**.
1. With regards to the obviousness rejection of claims 1-4, 6-10, 12-20, 31-46 and 51-55 in the previous office action, the applicants' arguments have been considered but are not found persuasive. The applicants' stated that the compounds encompassed by claim 1 and its dependent claims 2-4 are nowhere taught or even suggested by the '096 patent and the generic structure of the '096 patent includes a very large number of compounds many of which are not specifically exemplified are even remotely suggested by the disclosure. This is particularly the case with respect to the compounds defined by instant claim 1 which requires a carbonyl linker between the piperazine ring and the

Art Unit: 1624

phenyl ring illustrated in formula I, a $-CH_2-$ linker between the phenyl ring and the R^4 substituent, and the requirement that Q be an unsubstituted N-linked heterocyclyl selected from the Markush group recited in the claim. However, as the example 723 in column 19 has a carbonyl linker between the piperazine ring and the phenyl ring and the requirement that Q be an unsubstituted N-linked heterocyclyl such as the morpholin-1-yl set forth herein differs only in the $-CH_2-$ linker between the phenyl ring and Q. Examples 81, 109 and 110 in column 79 has a $-CH_2-$ linker between the phenyl ring and the R^4 substituent, and the requirement that Q be an unsubstituted N-linked heterocyclyl, i.e. 1-piperidyl; N-morpholinyl, 4-Me-piperazin-1-yl differs only in the carbonyl linker between the piperazine ring and the phenyl ring. The preferred embodiment of U.S. '096 defines the variables R^1 and R^{21} as follows: R^1 is cycloalkyl, alkyl or CN and R^{21} is H or R^1 and R^{21} together form $=CH_2$ or $=O$ in column 6, lines 34-36. The compounds, compositions and method of use of the compounds of formula I of the instant invention are generically embraced by U.S. '096 in view of the interchangeability of the substitutions of formula I. Thus, one of ordinary skill in the art at the time the invention was made would have been motivated to select for example a carbonyl linker between the piperazine ring and the phenyl ring illustrated in formula I as well as a $-CH_2-$ linker between the phenyl ring and the Q where Q can be an unsubstituted N-linked heterocyclyl as well as other possibilities from the generically disclosed alternatives of the reference and in so doing obtain the instant compounds in view of the equivalency teachings outlined above. Hence, one of ordinary skill in the art at the time the invention was made would have been motivated to select for example

instant X is O as well as other possibilities from the generically disclosed alternatives of the reference.

Claims 1-4, 41-43, 51-53 and newly added claims 56-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lowe et al., U.S. Patent No. 5,883,096, for reasons of record and stated above.

3. In view of the amendment dated March 14, 2007, the following new grounds of rejection apply:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-4, 42, 43 and 51-53 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendment to claim 1 where Q is the moieties diazepamyl or decahydroisoquinolin-2-yl is not described in the specification with respect to the genus.

Applicant is required to cancel the new matter in the reply to this Office action.

5. Claims 1-4, 22, 23, 25-30, 41-43, 51-53 and 56-62 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for other forms,

Art Unit: 1624

does not reasonably provide enablement for solvates. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. The claim is drawn to solvates. But the numerous examples presented all failed to produce a solvate. These cannot be simply willed into existence. As was stated in *Morton International Inc. v. Cardinal Chemical Co.*, 28 USPQ2d 1190 "The specification purports to teach, with over fifty examples, the preparation of the claimed compounds with the required connectivity. However ... there is no evidence that such compounds exist... the examples of the '881 patent do not produce the postulated compounds... there is ... no evidence that such compounds even exist." The same circumstance appears to be true here: there is no evidence that solvates of these compounds actually exist; if they did, they would have formed. Hence, applicants must show that solvates can be made, or limit the claims accordingly.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

6. Claims 1-4, 42, 43, 51-53, 59 and 60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

- a) Claim 1 and claims dependent thereon are vague and indefinite in that it is not known what is meant by alkyl, which appears after the deleted portion of the definition of Q.

- b) Claim 28 recites the limitation "(imidazolyl)C₁₋₃alkylene, 2,3-dihydro-indolyl, 2-oxobenzimidazolyl, (tetrazolyl)C₁₋₃alkylene, (triazolyl)C₁₋₃alkylene, (pyrrolyl)C₁₋₃alkylene and pyrrolidinyl" in the definition of R⁹. There is insufficient antecedent basis for this limitation in the claim.
- c) Claim 60 is vague and indefinite in that it is missing an open parenthesis in the nomenclature of the species.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1, 22, 23, 25-30, 42, 43, 51-53 and 56-59 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-29 of copending Application No. 11/531,849. Although the conflicting claims are not identical, they are not patentably distinct from each other because the

compounds, compositions and method of use of the compounds of formula (I) embrace the species of 11/531,849.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Election/Restrictions

8. Claims 47-50 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on March 16, 2006.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda L. Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic

Art Unit: 1624

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in black ink that reads "Brenda Coleman". The signature is fluid and cursive, with a long horizontal stroke at the end.

Brenda L. Coleman
Primary Examiner Art Unit 1624
Saturday, May 26, 2007